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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR    | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|-------------------------|---------------------|------------------|
| 09/581,331      | 07/21/2000  | Maarten Hendrik Stuiver | MOG57701/UST        | 6942             |

23698 7590 02/27/2002

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EXAMINER

LACOURCIERE, KAREN A

ART UNIT PAPER NUMBER

1635

DATE MAILED: 02/27/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/581,331

Applicant(s)

STUIVER ET AL.

Examiner

Karen Lacourciere

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 9-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 July 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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**DETAILED ACTION*****Election/Restriction***

Applicant's election with traverse of Group I in Paper No. 13 is acknowledged. The traversal is on the ground(s) that the claims of Group I and Group II are united by the inventive concept of using promoters and transcription-activating elements with complementary expression patterns. Applicant argues that the reference Gelvin et al., cited by the Examiner in the prior Office action (mailed 09-07-01) to support lack of unity of invention, does not disclose complementary expression patterns and, therefore, the special technical feature of the invention is not disclosed in the prior art. This is not found persuasive because "complementary expression patterns" has not been defined in the specification in a manner that would exclude the chimeric promoters disclosed by Gelvin et al. from claims 1 and 2. The promoters disclosed by Gelvin et al. would be encompassed by claims 1 and 2 and, therefore, the technical feature was disclosed in the prior art.

Further, lack of unity of invention does not require the disclosure of the reference Gelvin et al. The claims of Group I and Group II are not linked because the two groups are drawn to promoters comprising different promoter elements. For example, the promoters of Group I comprise elements of the ferredoxin and rolD promoters, which are not required for the promoters of Group II and the promoters of Group II comprise elements of the plastocyanin and

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the S-adenosyl-methionine-1 promoters, which are not required for the promoters of Group I, and, therefore, are not linked by the same technical feature.

The requirement is still deemed proper and is therefore made FINAL.



Applicant's argument that the invention of Claim 15, as amended, should be examined with the claims of Group I is found to be persuasive, however, the subject matter of claim 15 is generic to both Group I and Group II and will only be examined to the extent that it reads on the elected subject matter.

Claims 9-14 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 13.

The instant Office action is an examination on the merits of the subject matter of Group I, claims 1-8 and 15.

***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-8 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-8 and 15 are indefinite because of the absence of an article in the preamble of the claims, rendering the scope of the claims indefinite. The claims appear to follow the European style, whereas in U.S. practice independent claims normally contain an article in the preamble.

Claims 1 and 5 are indefinite due to the recitation "minimal promoter". The metes and bound of the term "minimal promoter" are unclear because there is no one art recognized definition for what elements of a promoter constitute a "minimal promoter" and the specification does not provide a definition that would define the boundaries of that term, for example, it would vary as to what basal elements of a promoter the skilled artisan would consider to be required for transcription. Claims 2-4, 6-8 and 15 are indefinite for the same reasons due to their dependence on claim 1.

Claim 1 is indefinite due to the recitation "complementary pattern". It is unclear what a "complementary pattern" of transcription for promoters would encompass, for example, expression of a particular promoter can vary under different conditions. For example, two promoters may drive expression in a tissue in a mature plant, but at a different developmental stage of the plant one of these promoters may be active and the other may be inactive, so under some conditions one skilled in the art would consider their expression to be "complementary", yet there is overlap in their expression under other conditions, so these promoters may not be

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considered complementary. Further, it is unclear if the level of expression level for promoters is considered in the evaluation of the pattern of expression, for example, although the specification defines expression patterns as being complementary when one promoter shows little overlap with the expression of the other promoter (see page 5, lines 17-20), it is unclear if that indicates that if two promoters have any level of transcription in the same cell tissue it would be considered overlap, hence not complementary, even if one promoter drives high levels of expression and the other promoter drives only very low levels of expression in the common tissue. The indefinite nature of the phrase "complementary pattern" becomes even more confusing when read in consideration of claim 2. It is unclear whether or not claim 2 further limits claim 1 because claim 2 is limited to promoters wherein each of the transcription-activating elements mediates transcriptional activation in most plant parts and, therefore, the transcription activating elements of claim 2 would overlap in their expression pattern and may not fall within the limitation of "complementary pattern" provided by claim 1, however, given the indefinite nature of the phrase "complementary pattern", the promoters of claim 2 may fall within the scope of claim 1. Claims 2-8 and 15 are indefinite for the same reasons due to their dependence on claim 1.

Claim 1 is indefinite because it is unclear what a complementary level of transcription would encompass, for example, does complementary level indicate one promoter is active while another is totally inactive or would it also encompass promoters which have high levels versus low levels of transcription and, if so, how are levels judged to be "complementary", for example,

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how large of a difference in levels of transcription are required to be considered "complementary".

Claims 2-8 and 15 are indefinite for the same reasons due to their dependence claim 1.

Claim 1 is unclear because it is unclear what "elements" are being referred to after the word "which" in line 3 of the claim. The claim recites "transcription-activating elements" (bridging lines 2 to 3), however, "transcription-activating elements" regulate the expression of proteins driven by a promoter and do not actually have an transcription pattern. It is unclear if "elements" refer the set of promoters which comprise the transcription-activating elements or if, for example, the minimal promoter also drives transcription with a pattern complementary to the set of promoters comprising the transcription-activating elements. Claims 2-8 and 15 are indefinite for the same reasons due to their dependence on claim 1.

Claim 1 is indefinite because the word "which" in line 3 is grammatically incorrect and renders the claim unclear. Claims 2-8 and 15 are indefinite for the same reasons because they are dependent on claim 1.

Claim 2 is indefinite due to the recitation "most plant parts". One skilled in the art would not know what number of plant parts would be considered to be "most" plant parts as "most" is a term of degree and one skilled in the art would not know what number of parts would be considered "most", or even how many total "parts" would be considered to be comprised in a plant.

Claim 3 is indefinite due to the recitation "specifically active". The metes and bounds of the term "specifically active" are unclear, for example, whether "specifically active" indicates

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absolute tissue specificity for a promoter, indicates a promoter drives expression of one specific protein in either underground or green parts of a plant, or if the activity is specific to a particular developmental stage within a green or underground part of a plant. Claims 4-8 are indefinite for the same reasons due to their dependence on claim 3.

Claim 3 recites the limitation "other promoter" in line 3 of the claim. There is insufficient antecedent basis for this limitation in the claim. Claim 3 is dependent on claim 1, which recites a set of promoters and a minimal promoter. It is unclear if "the other promoter" refers to the minimal promoter, or a promoter from the set of promoters. Further, the set of promoters in claim 1 is not limited to two promoters. If the "other promoter" refers to a promoter within the set of promoters, it is unclear which other promoter is being referred to or if it refers to all other promoters within the set of promoters. Claims 4-8 are indefinite for the same reasons due to their dependence on claim 3.

Claim 3 is indefinite because it is unclear if the word "while" indicates that the activity of the two promoters is condition or time dependent and interrelated. For example, does one promoter need to be activated in the green parts of a plant whenever the other promoter is activated in the underground parts of the plant, or, alternatively, if the activity of each promoter is independent (ie. one promoter is active in green parts of a plant and the other promoter is active in underground parts of a plant). Claims 4-8 are indefinite for the same reasons due to their dependence on claim 3.



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Claim 3 recites the limitation "the plant" bridging lines 2-3 of the claim. There is insufficient antecedent basis for this limitation in the claim. Claims 4-8 are indefinite for the same reasons due to their dependence on claim 3.

Claim 4 recites the limitation "the ferredoxine and the RolD promoter" bridging lines two and three of the claim. There is insufficient antecedent basis for these limitations in the claim.

Claim 5 recites the limitation "the minimal promoter element" in line two of the claim. There is insufficient antecedent basis for this limitation in the claim. Claim 5 depends from claim 1, which recites a minimal promoter and transcription-activating elements. It is unclear, for example, if the "minimal promoter element" refers to the minimal promoter of claim 1, a transactivating element from the minimal promoter or a transactivating element from the set of promoters.

Claim 5 is indefinite due to the recitation "derived from". It is unclear what types of changes and what degree of changes can be made to the minimal promoter element of a ferredoxin promoter and still be encompassed by the term "derived from the ferredoxin promoter".

Claim 6 is indefinite due to the recitation "derived from". It is unclear what types of changes and what degree of changes can be made to an *Arabidopsis thaliana* ferredoxin promoter and still be encompassed by the term "derived from *Arabidopsis thaliana*". Claims 7 and 8 are indefinite for the same reasons due to their dependence on claim 6.

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Claim 15 recites the limitation "the promoter of claim 1" in line two of the claim. There is insufficient antecedent basis for this limitation in the claim. Claim 1 recites a chimaeric plant promoter and a minimal promoter, it is unclear what promoter "the promoter" is referring to.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Gelvin et al. (WO 95/14098, cited on PTO form 1449, filed Sept. 15, 2000), as evidenced by Kononowicz et al. (reference cited on PTO form 1449, filed Sept. 15, 2000). Kononowicz et al. is cited to support the inherency of the expression pattern of the ocs promoter

Gelvin et al. disclose chimaeric plant promoters that comprise a minimal promoter, a transcriptional enhancer element (UAS) from a mannopine synthase gene (mas) and a transcriptional enhancer element from an opine synthase gene (ocs). Gelvin et al. disclose that the mas promoter has strong expression in roots and weak expression in leaves (see for example page 3, lines 20-21). Gelvin et al. do not explicitly state that the ocs promoter has an expression pattern "complementary" to the expression pattern of the mas promoter and is specifically active in green parts of the plant, however, Kononowicz et al. is provided as evidence that the

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expression pattern inherent to the ocs promoter fulfills the limitations of the claim. Kononowicz et al. indicates that the ocs comprises an upstream activating sequence that directs expression of the ocs promoter such that it is active in specific cells in leaves stems and roots. The expression of the ocs promoter is especially strong in vascular tissue of the leaves, leaf mesophyll cells, and leaf and stem guard cells, which are areas mas promoter would be expected to be weak, based on the disclosure of Gelvin and would, therefore, the mas and ocs promoters would be considered to have a “complementary pattern and level of transcription”. Gelvin et al. disclose that the mas and ocs promoter UAS elements direct a level of expression greater than 1% in “most” tissues, relative to the tissues wherein they are most active (see for example page 21 and figures 2 and 3). Gelvin et al. further disclose these chimaeric promoters in constructs for the expression of genes in plants. Therefore, Gelvin et al. anticipates claims 1-3 and 15.

### ***Claim Objections***

Claim 4 is objected to because of the following informalities: The word “ferredoxine” should be corrected to read “ferredoxin”. Appropriate correction is required.

### ***Conclusion***

Nucleic acids comprising SEQ ID NO: 3 and nucleic acids comprising both SEQ ID NO: 1 and 2 are free of the prior art.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Lacourciere whose telephone number is (703) 308-7523. The Examiner can normally be reached from 8:30 am to 6:30 pm, Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached at (703) 308-0447. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Karen A. Lacourciere  
Patent Examiner TC 1600

KAL  
February 25, 2002